8EHQ-0695-13464

Great Lakes
Chemical Corporation

P.O. BOX 2200 • ONE GREAT LAKES BOULEVARD • WEST LAFAYETTE, IN 47906 • PHONE: 317-497-6100 • FAX: 317-497-6123

16 May 1995

ORIGINAL

RECEIVED
OPPT CBIC
95 JUN 23 AM 11:42

Document Control Office (7404)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

Contains No CBI

ATTN: TSCA Section 8(e) Coordinator
(When responding, please refer to JAB-95-94)

Gentlemen:

Great Lakes Chemical Corporation is submitting a TSCA Section 8(e) substantial risk notification concerning an acute inhalation LC_{50} study in rats with BCDMH (bromo-chloro-5,5-dimethylhydantoin). The study was performed to fulfill EPA FIFRA pesticide reregistration requirements. Because there are non-pesticide uses of this product, we are submitting this study to meet TSCA reporting obligations. The following information was received via an unaudited draft report by Great Lakes Chemical Corporation on May 4, 1995 from the contract laboratory performing the study. The PMN for BCDMH is P-94-34.

The test article was administered as an aerolized dust particulate (airmilled) to groups of rats via a nose-only chamber. Three groups of ten rats each were exposed to a target concentration of either 0.100, 0.170, or 0.300 mg of BCDMH per liter of air. Achieved airborne concentrations (gravimetrically determined) were 0.11, 0.16, and 0.29 mg/L. The average mass median aerodynamic diameters for the individual exposures ranged from 1.5 to 1.7 microns.

All deaths occurred within one day of exposure. Mortality was 0, 3, and 10 of 10 for the concentrations of 0.11, 0.16, and 0.29 mg/L, respectively. During exposure, clinical observations were recorded for the 0.16 and 0.29 mg/L groups. No abnormal clinical observations were noted in the 0.11 mg/L group. Clinical findings in the two (2) higher concentration exposure groups included labored and/or shallow respirations with or without rales, hypothermia, prostration, and tremors in two (2) or more animals. In addition, various external matting (dried red material around nose and/or eyes, and dried yellow urogenital material) was noted for several animals through study day 2.

RECEIVED
OPPT NCIC
95 JUN 28 AM 11:11

At necropsy, all animals that expired had red or mottled lungs (all lobes). One animal (0.16 mg/L male) had an enlarged thymus gland. There were no gross findings for the animals that survived to study termination.

Based on combined data, the acute inhalation LC_{50} of BCDMH for male and female rats is 0.168 mg/L with 95% confidence limits of 0.155 to 0.182 mg/L for a single, four-hour exposure period.

It should be noted by the Agency that the above data is entirely focused on bulk-powder BCDMH and to perform this study had to be airmilled to achieve a MMAD between 1 and 2 microns during each of the exposures. Because it was necessary to airmill the test material to acquire the reported MMADs ranging from 1.5 to 1.7 microns, we believe this suggests the majority of the material either consists of non-respirable particles or respirable ones that form non-respirable agglomerates, which are difficult to fractionate apart.

If you have any questions, please feel free to contact me at (317) 497-6223.

Sincerely,

John A. Biesemeier

John A. Biesemeier
Regulatory Toxicologist
Regulatory Affairs

JAB/clw

cc: PMN P-94-34 File